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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,411	12/15/2003	James W. Nicholson	P1682 US (2650/191)	3962

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,411

Applicant(s)

NICHOLSON ET AL.

Examiner

Tuan V. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/18/05, 12/15/03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
2. **Claims 1-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Douk et al (U.S. 6,911,036).**
3. Referring to claim 1, Douk et al disclose a system for treating a vascular condition (see Figs. 4 and 5), the system comprising: a hollow Guidewire 144; a core wire 142 inserted through the hollow guidewire, the core wire including a undulating section 160 carried within the hollow guidewire; and an embolic filter device 25 or occluder device 320 (see Fig.13 and col 8, lines 54-55) coupled between a distal end 27 of the hollow guidewire and a distal end 48 of the core wire, wherein the undulating section 160 of the core wire provides frictional control of the embolic containment device based on a direction of axial translation within the hollow guidewire. The undulating section 160 is frictionally contacted an inner surface of the hollow guidewire (see col 4, line 11 to col 5, line 53). It would have been an obvious design choice to one of ordinary skill in the art to use tapered undulating

section wherein an amplitude of each consecutive undulation varies linearly with axial distance from a proximal end of the core wire to replace the constanced undulating section as described by Douk et al since such a design does not provide any advantage over Douk's design. Each undulation or crest of the tapered undulating section will have a friction force that corresponding to the amplitude of that crest. Frictional force between the undulation and the inner surface of hollow guidewire is depended on the amplitude of the undulation. Highest amplitude will generate highest frictional force, lowest amplitude will generate smallest frictional force. Since the amplitude of each consecutive undulation increases or decreases linearly with the axial distance therefore the resulting force generated by the tapered undulating section will be the sum of frictional forces generated by each undulation. The resulting force generated by the tapered undulating section can be achieved by Douk's design with a routine experiment.

4. Referring to claims 2-9, 11-14, they are rejected for the same reasons as claim 1.
5. Referring to claim 15, Douk et al disclose the coating disposed on the core wire to reduce friction between the core wire and hollow guidewire (see col 7, lines 10-15).
6. Referring to claims 16-19, Douk et al disclose a method for treating a vascular condition (see Figs. 4 and 5) the method comprising: providing a core wire 142 inserted through a hollow guidewire 144, the core wire including an undulating section 160 carried within the hollow guidewire; providing an embolic containment

device 25 coupled between a distal end 48 of the hollow guidewire and a distal end 27 of the core wire; axially translating the core wire in a first direction relative to the hollow guidewire; expanding the embolic containment device based on the axial translation in the first direction; and controlling the axial translation in the first direction based on frictional resistance between the undulating section and an internal surface of the hollow guidewire. The method further comprising: capturing embolic material when the embolic containment device is expanded. The method further comprising: axially translating the core wire 142 in a second direction relative to the hollow guidewire 144; contracting the embolic containment device 25 within the vessel based on the axial translation in the second direction; and controlling the axial translation in the second direction based on frictional resistance between the undulating section and the internal surface of the hollow guidewire (see col 4, line 11 to col 5, line 8 and col 11, line 45 to col 12, line 2).

7. **Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Douk et al (U.S. 6,911,036).**
8. Referring to claim 20, Douk et al disclose a system for treating a vascular condition (see Figs. 4 and 5), the system comprising: a hollow Guidewire 144; a core wire 142 inserted through the hollow guidewire, the core wire including an undulating section 160 carried within the hollow guidewire for providing frictional control of the expansion and contraction of an embolic containment device 25 or occluder device based on a direction of axial translation within the hollow

guidewire. The undulating section 160 is frictionally contacted an inner surface of the hollow guidewire (see col 4, line 11 to col 5, line 8).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al (U.S. 6,911,036) further in view of Dubrul (Pub. No. U.S. 2004/0236369 A1, this application claims the benefit of Provisional application No. 60/083,178, filed on April 27, 1998. Provisional application No. 60/095,106, filed on August 3, 1988. Provisional application No. 60/115,548, filed on January 12, 1999).

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12. Referring to claim 10, Douk et al disclose the invention substantially as claimed except for the filter includes a braided wire mesh, and wherein at least a portion of the braided wire mesh is coated with elastomeric material. Dubrul discloses the embolic filter includes a braided wire mesh, and wherein at least a portion of the braided wire mesh is coated with elastomeric material (see paragraph [0057] and [0063]). It would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the filter, as disclosed by Dubrul, to incorporate into the device, as disclosed by Douk et al because this will reduce the friction between the filament.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,270,513 to Tsugita et al.

U.S. Patent No. 5,497,782 to Fugoso.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
December 9, 2005

TV


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/12/05